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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,901

04/20/2006

Michael Joseph Coghlan

X-16398

5935

25885 7590 03/17/2008

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PATENT DIVISION

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

03/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/576,901	Applicant(s) COGLAN ET AL.	
	Examiner Taofiq A. Solola	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9 and 14-18 is/are rejected.
- 7) ☐ Claim(s) 10-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-18 are pending in this application.

Claims 19-23 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tewari et al., *Studies on Betaine Decomposition of Arsonium Ylides*, Anorg. Chem. Org. Chem., (1980), Vol. 35 (1) pp. 95-98, and Tagaki et al., J. Am. Chem. Soc. (1983), Vol. 105(14), pp. 4676-4684, individually in view of King, Med. Chem.: Principle and Practice (1994), p. 206-208.

Applicant claims compounds of formula I and their compositions, wherein Z is S, O, or CH₂ and R₂ is m-OH or m-alkoxy.

Determination of the scope and content of the prior art (MPEP 2141.01)

Tewari et al., teach similar compounds and composition thereof wherein Z is CH₂ or O, and R₂ is 3-Cl or 4-Cl. See compounds 11a and 13a. (Claims 1-5, 6-8, 15-18).

Tagaki et al., teach similar compounds and composition thereof wherein Z is CH₂ and R₂ is m-F or p-alkoxy. See compounds 4 and 6. (Claims 1-9, 14-18).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Tewari et al., is that applicant claims Z is S, O, or CH₂ instead of Z is CH₂ or O by Tewari et al. Applicant also claims 3-OH at R₂ instead of 3-Cl by Tewari et al.

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The difference between the instant invention and that of Tagaki et al., is that Applicant also claims m-OH instead of m-F by Tagaki et al. Also, compound 6 of Tagaki et al., has alkyl instead of H by applicant when Z is CH₂.

Applicant's also claims position isomers of the compounds Tewari et al and Takagi et al.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, King teaches that replacement of Cl or F with OH, or replacement of CH₂ or O with S is expected to produce compounds having similar biological activity (bioisosterism). See page 208, univalent atoms and ring equivalents. See also, *Ex parte Engelhardt*, 208 USPQ 343 (Bd. Pat. App. & Int., 1980); *In re Merck*, 231 USPQ 375 (Fed. Cir., 1986).

Also, H and alkyl are art recognized equivalents. *In re Lincoln*, 126 USPQ 477, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960).

A novel and useful compound, which is an isomer of a compound of prior art, is prima facie obvious. *In re Norris*, 84 USPQ 458 (1950).

Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art would have known to make all the changes to the compounds of the prior arts at the time the invention was made. The motivation is from knowing that H and alkyl are equivalents, replacing Cl or F with OH or replacing CH₂ or O with S would produce compounds having similar biological properties, and from the expectation that position isomers would have similar biological and/or chemical properties.

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Objection

Claims 10-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Argument

Applicant's arguments filed 1/14/08 have been fully considered but they are not persuasive. Applicant contends the prior arts fail to disclose utilities for their compounds and, therefore there is no motivation to modify the compounds and no expectation of successful utility thereof. This is not persuasive because various derivatives of the compounds are well known in the art to have affinity for steroid hormone nuclear receptors. For example, see Buu-Hoi et al., J. Org. Chem. (1957), Vol. 22, pp. 1057-59, and US 2,891,957.

Given the teachings of the prior arts and knowledge of isomerism and bioisosteres equivalents it would have been obvious to try making the instant replacements and claim the instant isomers at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, 1625

March 5, 2008

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The claims